



# Drug Discovery

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## FDA Approved Drugs – January 2016

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### General Note

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### ONZETRA XSAIL (SUMATRIPTAN NASAL POWDER)

**Company:** Avanir; Approved by January 2016

**Specific Treatments:** migraine

### General Information

Onzetta Xsail is specifically indicated for the acute treatment of migraine with or without aura in adults. It is supplied as a powder for intranasal administration, delivered with the Xsail breath-powered delivery device only. The recommended dose is 22 mg, administered by use of one nosepiece (11 mg) in each nostril. The maximum dose in a 24-hour period should not exceed two doses (44 mg) separated by at least 2 hours.

### Mechanism of Action

Onzetta Xsail is a nasal powder formulation of sumatriptan, a serotonin 5-HT1B/1D receptor agonist. Sumatriptan binds with high affinity to human cloned 5-HT1B/1D receptors. Sumatriptan presumably exerts its therapeutic effects in the treatment of migraine

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headache through agonist effects at the 5-HT1B/1D receptors on intracranial blood vessels and sensory nerves of the trigeminal system, which result in cranial vessel constriction and inhibition of proinflammatory neuropeptide release.

#### **Side Effects**

Adverse effects associated with the use of Onzetta Xsail may include: abnormal taste, nasal discomfort, rhinorrhea, rhinitis

### **ZEPATIER (ELBASVIR AND GRAZOPREVIR)**

**Company:** Merck; Approved by January 2016

**Specific Treatments:** chronic HCV genotypes 1 or 4

#### **General Information**

Zepatier is specifically indicated with or without ribavirin for the treatment of chronic HCV genotypes 1 or 4 infection in adults. It is supplied as a tablet for oral administration. Recommended dosage: One tablet taken orally once daily with or without food. Please see drug label for dosage regimens and durations for patients with Genotype 1 or 4 HCV with or without cirrhosis.

#### **Mechanism of Action**

Zepatier is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor.

#### **Side Effects**

Adverse effects associated with the use of Zepatier may include: fatigue, headache, nausea, anemia.